Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee
February 3, 2009
Hilton Washington DC/Silver Spring, Maryland Ballroom
8727 Colesville Road, Silver Spring MD

Agenda

8:00 a.m.	Call to Order Introduction of Committee	**Marvin A. Konstam, M.D** Acting Chair
	Conflict of Interest Statement	**Elaine Ferguson, M.S.,R.Ph.** Designated Federal Official, CRDAC

The committee will discuss new drug application (NDA) 22-307, prasugrel hydrochloride film coated oral tablets, 5 milligrams (mg) and 10 mg, for the proposed indication for use in acute coronary syndrome.

8:05 a.m.	FDA Opening Remarks	**Norman Stockbridge, M.D.** Director, Cardiovascular and Renal Drug Products, CDER
8:15 a.m.	**Sponsor Presentations**	
	Introduction	**J. Anthony Ware, MD** Vice President, Lilly Research Laboratories Diabetes, Cardiovascular, and Acute Care Platform
	Unmet Medical Need	**Eugene Braunwald, M.D.** Hersey Distinguished Professor of Theory and Practice of Medicine, Harvard Medical School Chairman, TIMI Study Group, Brigham and Women's Hospital
	Dosing Considerations	**Jeffrey Riesmeyer, M.D**. Medical Fellow, Cardiovascular Medicine Eli Lilly and Company
	Benefit-Risk (TRITON-TIMI 38)	**Elliott M. Antman, M.D.** Professor of Medicine, Harvard Medical School Senior Investigator, TIMI Director of Samuel A. Levine Cardiac Unit, Brigham and Women's Hospitals
	Special Topics	**William Macias, M.D., Ph.D.** Senior Medical Director, Cardiovascular Acute Care Eli Lilly and Company
	Closing Remarks	**Eugene Braunwald, M.D**.

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9:45 a.m.	Questions to presenters	
10:15 a.m.	**Break**	
10:30 a.m.	**FDA Presentation**	**Ellis F. Unger, M.D.** Deputy Director Division of Cardiovascular and Renal Products Office of Drug Evaluation-I Office of New Drugs CDER, FDA
11:30 a.m.	Questions to presenters	
12:00	**Lunch**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Discussion of questions to committee	
3:30 p.m.	**Break**	
3:45 p.m.	Discussion of questions to committee (continued)	
5:00 p.m.	Adjourn	